

Case Study # 10 : Public-Private partnerships.

Dr. So-and-So in the NIH IRP is approached by a company whose management has been following his lab's work for several years. The company makes novel reagents and a platform likely to be useful in Dr. S's work, but which are too expensive for him to readily obtain. They offer a partnership with his lab and the NIH, providing reagents and analytical work for free. In return, they ask that he acknowledge their contribution in his papers and that he speak at meetings on their behalf.

Is this a partnership?

Maybe- it depends on to what degree this is merely a transfer of materials and specifically requested analyses vs. a collaborative design process involving initial and ongoing input from the company scientists. Alternatively, it could be structured as an MTA (if it only involves the transfer of reagents); as a CRADA (depending on the intellectual property issues relating to inventions and licensing related to the projects outcomes); or as a gift- if the reagents and/or analyses are donated as (in kind) gifts to the IC. It would be considered a partnership if there were ongoing interactions relating to the design and conduct of the research by both parties. (PPP manual chapter(MC) in development)

Can the arrangement proceed?

Possibly, but only after considering several important issues. Among them:

- Does Dr. S. have any personal financial or interpersonal relationships with the company that are likely to substantially affected by entering into this agreement?
- Will there be a real or apparent conflict of interest as a result of this activity?
- Has he provided equal opportunity and fair access to other companies with similar reagents and capabilities (fair access and inclusivity)?
- Is this science consistent with the program and mandate of his IC and lab?
- Does the conduct of this research represent an NIH program priority?
- Can this science be accomplished better, more cheaply and/or more rapidly by entering into a partnership?
- Does the design of the relationship ensure that no outside parties unduly influence the allocation of government funds?
- Will there be open and public access to the results of the activity?
- Does the donor/partner receive a *quid pro quo* as a result of the donation/partnership?

Can he speak on the company's behalf at scientific meetings?

Dr. S can present his data and results at scientific meetings and in the literature in accordance with his IC's policies regarding presentation and publication. He can acknowledge the contribution of reagents and analysis by the company, but cannot speak on the company's behalf. Dr. S remains a government scientist and is obligated to present his results fairly and completely. The company cannot seek or obtain rights to influence or limit his presentations, this would represent an unacceptable *quid pro quo*.

Who can make the decision to enter into a partnership?

If this is an MTA or a CRADA, the usual procedures arranged through the IC technology transfer officer need to be completed.

If this is a partnership, the oversight will include the lab chief/branch chief, the SD and the IC Director, who ultimately needs to sign the MOU memorializing the partnership. Guidance from the Office of the General Counsel and the Public-Private Partnership Program should be sought to ensure the agreements are consistent with NIH regulations and policies.

If a gift is made to the institute, the gift regulations would apply to the acceptance of the gift (see xxx:).

What does it depend on?

The decision to enter into a partnership is, first of all, scientifically driven: ensuring that scientific rigor in the interest of the public health is served in this arrangement. Once that has been determined, the details of the arrangement need to explicitly describe the roles and contributions of all the partners, affirm that U.S. laws and regulations and NIH policies will be adhered to, and define the outcomes of the partnership.

What agreements need to be in place?

Partnerships are generally memorialized in Memoranda of Understanding (MOU MC in development) entered into by the parties involved (i.e., the company and the institute). PPP program staff and OGC should be consulted in the development of a partnership and in the drafting and execution of MOUs. If the arrangement is conducted as a CRADA or MTA, then the IC technology transfer office will initiate the process to establish these agreements.

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